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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,959	01/20/2004	Michael A. Martinelli		1480

7590 04/14/2006

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EXAMINER	
JOHNSON III, HENRY M	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,959	MARTINELLI, MICHAEL A.	
	Examiner	Art Unit	
	Henry M. Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33* is/are allowed.

6)☒ Claim(s) *24-32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 2/27/2006 have been fully considered but they are not persuasive. The means for including a drug for moderating the cooling is not disclosed for the apparatus. The cooling means disclosed in the apparatus includes a closed circulation of fluid. A means for deploying a dopamine receptor blocker is not part of the disclosed apparatus.

Claim Objections

Claim 28 is objected to because of the following informalities: the word include in line 2 should be includes. Appropriate correction is required.

Claim 29 is objected to because of the following informalities: the word include in line 2 should be includes. Appropriate correction is required.

Claim 30 is objected to because of the following informalities: the word include in line 2 should be includes. Appropriate correction is required.

Claim 31 is objected to because of the following informalities: the word include in line 2 should be includes. Appropriate correction is required.

Claim 32 is objected to because of the following informalities: the word include in line 2 should be includes. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-32 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Means for delivery of a therapeutic drug is new matter not originally disclosed as part of the apparatus.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,931,047 to Broadwin et al. in view of U.S. Patent 6,203,540 to Weber and further in view of U.S. Patent 6,165,172 to Farley et al. Broadwin et al. teach an apparatus for delivering RF energy and ultrasonic energy to a target tissue site (abstract) with a fluid that cools the tip and the blood and tissue particles (Col. 3, lines 57-62). A probe tip provides the means for delivery of the plurality of energy and control of the electrosurgical unit is disclosed. Broadwin et al. does not teach delivery of the energy in pulses or means for sensing the temperature of the tissue. Weber teaches an apparatus for delivery of energy to tissue, the energy being ultrasonic energy and laser delivered in pulses (Col. 7, lines 40-43). The apparatus includes sensors for determination of tissue temperature (Fig. 3, # 25). Neither Broadwin et al. nor Weber teach a means for delivery of a drug with the energy. Farley et al. disclose a catheter for delivery of HF energy to a patient with port for delivery of therapeutic agents (Col. 6, lines 51-52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the temperature sensor and pulsed delivery as taught by Weber and the

delivery ports as taught by Farley et al. in the invention of Broadwin et al. as artisans skilled in the art are cognizant of the various parameters used for energy delivery such as pulse duration and rate and the benefits of providing feedback using temperature measurement. Further, the introduction of agents to cool tissue, aid thermal transfer or for therapeutic benefits is also well known in the arts and an artisan would be motivated to look to others for such techniques to benefit from all the techniques.

Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,931,047 to Broadwin et al. in view of U.S. Patent 6,203,540 to Weber in view of U.S. Patent 6,165,172 to Farley et al., as applied to claim 24 above, and further in view of U.S. Patent 6,506,189 to Rittman et al. Broadwin et al., Weber and Farley et al. are discussed above, but do not teach a computer for control or planar electrodes. Rittman et al. teach the delivery of RF energy to tissue via electrodes, the energy controlled by a microprocessor that includes temperature feedback (Fig. 2). Alternatives to RF energy are disclosed as microwave, laser, ultrasound, or other direct or alternating current power source (Col. 12, lines 14-18). A cooling means is disclosed, also controlled by the microprocessor (Fig. 2, # FS) that is clearly a temperature controlled fluid in thermal contact with the tissue. The microprocessor provides the means for controlling the energy to the tissue and has the capability to provide any temperature profile that is programmed into the microprocessor, including sequencing and waveform algorithms. The programming of temperature profiles is well known. Rittman et al. discloses flat or planar electrodes (Fig. 6, #s 132 & 152). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the well known computer control of the energy and planar electrodes as taught by Rittman et al. in the invention of Broadwin et al./Weber/Farley et al. to insure delivery of the energy in a concisely controlled manner. Electrodes of a wide variety of shapes are common and the shape is adapted based on the

specific target to be treated. One skilled in the art would look to other electrode configurations in the art.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,931,047 to Broadwin et al. in view of U.S. Patent 6,203,540 to Weber in view of U.S. Patent 6,165,172 to Farley et al., as applied to claim 24 above, and further in view of U.S. Patent 5,891,134 to Goble et al. Broadwin et al. and Weber are discussed above, but do not disclose cylindrical or spherical electrodes. As previously discussed, many shapes of electrodes are common in the art. Goble et al. discloses expandable electrodes (Figs. 9a & 9b). The shape is interpreted as either cylindrical or spherical. Electrodes on flexible or expandable structures are well known in the art and therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the electrodes as taught by Goble et al. in the device of Broadwin et al./Weber/Farley et al. as electrodes of a wide variety of shapes are common and the shape is adapted based on a specific target to be treated.

Allowable Subject Matter

Claim 33 is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

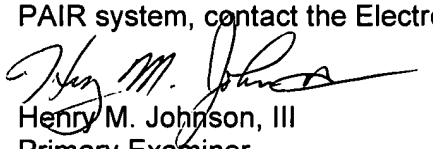
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Henry M. Johnson, III
Primary Examiner
Art Unit 3739